Boston Scientific Corporation

510(k) Summary for Blue SUI Sling

OCT 10 2012

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Janet A. McGrath
Principal Specialist Global Regulatory Affairs
508-683-4726
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename:	Obtryx II System
Common/usual name:	Surgical Mesh
Classification Name:	OTN – Mesh, Surgical, Synthetic, Urogynecologic, for Stress Urinary Incontinence, Female, Multi-Incision 21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename:	Advantage , Advantage Fit & Lynx Systems Obtryx, Prefyx Systems
Common/usual name:	Surgical Mesh
Classification Name:	FTL- Mesh, Surgical, Polymeric 21 CFR 878.3300, Class II
Premarket Notification:	Boston Scientific Corporation, ▪ K020110 ▪ K040787

E. Device Description

The proposed sling is a sterile, single use device, consisting of a synthetic mesh sling assembly and packaged with a delivery device. The mesh assembly consists of a blue knitted polypropylene monofilament fiber mesh body implant, association loops, dilator legs, sleeves, leader loops, center tab and lead.

The proposed sling is packaged with (2) delivery devices (Halo or Curved) which are used in conjunction with the mesh assembly to place the mesh implant. Each of the delivery devices consist of a polymer handle and a stainless steel needle which extends from the handle. The tip of the needle has a slot which is used to attach the association loop of the mesh assembly.

F. Intended Use

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

G. Technological Characteristics

The proposed sling has the same and/or equivalent technological characteristics (i.e. mesh design and mesh material) as the predicates K020110 & K040787.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed sling is substantially equivalent to the predicate sling in terms of intended use, technological characteristics, and performance characteristics tested. The proposed sling is as safe, as effective, and performs as well as the predicate devices.

I. Non-Clinicial Testing

Material testing was performed to demostrate that the material properites are suitable for the intended use.

Bench testing was performed to demostrate that the device as manufactured meets performance specifications. Test results demostrate that the device meets the predetermine specifications and is acceptable for clinical use.

Biocompatiblity testing was performed in accordance to standard EN ISO 10993-1 for each of the patient contacting materials, and results demonstrate that the device is biocompatible for its intended use.

Conclusion:

Based on material, biocompatiblity, bench testing, and the proposed device labeling, the Obtryx II System is substantially equivalent to the identified predicate devices in terms of intended, use , safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 10 2012

Ms. Janet A. McGrath
Principal Specialist Global Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way, M21
MARLBOROUGH MA 01752

Re: K121754
Trade/Device Name: Obtryx II System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: September 19, 2012
Received: September 20, 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Boston Scientific Corporation

Indications for Use Statement

510(k) Number (if Known): K121754

Device Name: Obtryx II System

Indications For Use:

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Prescription Use __X____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

09 Oct 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121754